K001577

JAN 11 2001



## VIII. 510(K) SUMMARY

**A. Sponsor/Submitter:**

Perclose
400 Saginaw Drive
Redwood City, CA 94063
Tel: (650) 474-3000
Fax: (650) 474-3012

**B. Contact Person:**

Daun S. Putnam
Regulatory Affairs Coordinator
(650) 474-3135

**C. Date of Submission:** May 19, 2000

**D. Trade (Brand) Name:** Outback™ Catheter

**E. Common Name:** Percutaneous Catheter

**F. Classification:** Class II

**G. Classification Name:** Percutaneous Catheter, 21 CFR Part 870.1250

**H. Product Code:** 74DQY

**I. Predicate Devices:**

1. Cordis Vista Brite Tip™ Guiding Catheter (K971572)
2. Scimed 7F Wiseguide™ Guide Catheter (K974684)

**J. Intended Use:**

The Outback catheter is intended to facilitate placement and positioning of catheters within the peripheral vasculature. The Outback catheter is not intended for use in the coronary or cerebral vasculature.

## K. Device Description:

The Outback catheter features a 4 Fr. steel-braided polyimide shaft through which a single-lumen steel-braided polyimide guide is housed. The guide is extendable and steerable from the tip of the catheter shaft, and features a radiopaque beveled guide tip allowing for visualization under fluoroscopy. A radiopaque index on the catheter shaft is oriented to the steerable guide tip. The proximal end of the Outback catheter features a rotating hemostasis valve through which the guide is extended and retracted via an attached control knob.

## L. Summary of Substantial Equivalence:

Perclose has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that the Outback catheter is substantially equivalent to currently marketed predicate devices.

The Outback catheter has essentially the same intended use as the predicate devices. Questions regarding the effects of any new technological characteristics of the Outback catheter have been answered through accepted scientific methods. These methods assessed new characteristics with regard to safety, functionality and reliability under simulated conditions of use. Results of scientific testing have ensured that all materials are biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use.

In conclusion, the Outback catheter has been shown to be substantially equivalent to the Class II predicates on which the device is based.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2001

Ms. Daun S. Putman
Regulatory Affairs Coordinator
Perclose, Inc.
400 Saginaw Drive
Redwood City, CA 94063

Re: K001577
Trade Name: Outback™ Catheter
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: October 23, 2000
Received: October 25, 2000

Dear Ms. Putman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## VII. INDICATIONS FOR USE STATEMENT

**510(k) Number:** To Be Determined

**Device Name:** Outback™ Catheter

**Indications for Use:** The Outback catheter is intended to facilitate placement and positioning of catheters within the peripheral vasculature. The Outback catheter is not intended for use in the coronary or cerebral vasculature.

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(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001577